

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9219

Bartle, J.

March 16, 2014

Frederick W. Schaupp ("Mr. Schaupp" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Rebecca Schaupp, Mr. Schaupp's spouse, also submitted a derivative claim for benefits. The Show Cause Record reflects that the Trust determined claimant's spouse was not entitled to derivative benefits as a matter of state law because she passed away before Mr. Schaupp had the surgery that is the subject of this claim. As claimant did not contest this determination of the Trust, the court need not address this issue.

support his claim for Matrix Compensation Benefits ("Matrix Benefits").³

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2011, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated July 2, 2002, Dr. Muttreja attested in Part II of claimant's Green Form that Mr. Schaupp suffered from mild aortic regurgitation and had

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$342,264.⁴

In the report of claimant's August 17, 2011 echocardiogram, the reviewing cardiologist, Rajeev K. Garg, M.D., stated:

The flow through the stenotic valve was highly turbulent with a peak gradient of 49.8 mmHg, mean gradient of 36.8 mmHg, with an aortic valve area of about 0.9 sq cm by planimetry and about 0.8 sq cm by the continuity equation.

Dr. Muttreja, however, attested in claimant's Green Form that Mr. Schaupp did not suffer from aortic stenosis. Under the Settlement Agreement, the presence of aortic stenosis, which is defined as "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation," requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)e). As the Trust does not contest Mr. Schaupp's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In April, 2012, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., one of its auditing

4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical basis for Dr. Muttreja's finding that claimant did not have aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation. In support of this conclusion, Dr. Parmar explained:

The [transthoracic echocardiogram] of 7/20/11 and [transesophageal echocardiogram] of 8/17/11 shows aortic stenosis and depressed ejection fraction is the 35% range.

....

There is evidence of aortic Stenosis by [transesophageal echocardiogram] 8/17/11 and by [dobutamine stress echocardiogram] 7/20/11. The [transthoracic echocardiogram] of 7/2/02 showed aortic sclerosis without stenosis.

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination that Mr. Schaupp was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant argued that he was entitled to Matrix A-1 benefits because Dr. Parmar failed to determine the presence of aortic stenosis by the Continuity Equation, the only method provided for in the Settlement Agreement. Claimant also argued that the Trust

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Schaupp's claim.

improperly used more recent echocardiograms to find the presence of aortic stenosis.⁶

The Trust then issued a final post-audit determination, again determining that Mr. Schaupp was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Schaupp's claim should be paid. On November 19, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8968 (Nov. 19, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 14, 2013, and claimant submitted a sur-reply on March 27, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and

6. In addition, claimant asserted that a reduction factor, such as aortic stenosis, should not reduce a claim to the B Matrix unless the reduction factor was present at the time claimant was first diagnosed as FDA positive. We, however, have rejected this argument. See, e.g., PTO No. 8822, at 9-12 (Feb. 22, 2012), aff'd, 525 F. App'x 140 (3d Cir. 2013).

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the
(continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

In support of his claim, claimant reasserts the arguments that he made during contest.⁸ In response, the Trust argues that Mr. Schaupp's claim properly was reduced to Matrix B-1 because claimant had aortic stenosis prior to his aortic valve surgery. The Trust also argues that claimant did not present any expert opinion to support his assertion that the auditing cardiologist did not use the Continuity Equation to find the presence of aortic stenosis.

7. (...continued)

jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

8. Claimant also asserts that the Seventh Amendment to the Settlement Agreement "guaranteed" claimants full Matrix Benefits. Nothing in the Seventh Amendment, however, guarantees a claimant full Matrix Benefits for a claim or that a claim always is payable on the A Matrix. As the Seventh Amendment states, determinations and actions as to Category One class members "shall have no preclusive or precedential effect of any kind on the Trust in the administration of claims for ... Seventh Amendment Matrix Compensation Benefits." Seventh Amendment § IX.E. Thus, claimants must still establish their entitlement to such benefits.

In his sur-reply, claimant argues that it was the Trust's obligation to establish that the auditing cardiologist used the Continuity Equation to determine the presence of aortic stenosis as defined by the Settlement Agreement. Claimant also argues that the Trust misstates the standard for determining when a reasonable medical basis exists for an attesting physician's finding and that deference is to be given to the attesting physician's opinion.

The Technical Advisor, Dr. Vigilante, reviewed claimant's August 17, 2011 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have aortic stenosis as defined by the Settlement Agreement. Specifically, Dr. Vigilante stated, in pertinent part:

An excellent Doppler signal of the left ventricular outflow tract was noted in a transgastric view using pulse wave Doppler. The maximum velocity of the left ventricular outflow tract flow was 0.9 meters per second. I measured the left ventricular outflow tract velocity time integral at 23.8 cm. This correlates well with the sonographer-determined velocity time integral of 23.1 cm. There were excellent images of the continuous wave Doppler velocity across the stenotic aortic valve. I determined that the peak aortic valve velocity was 3.7 meters per second. I determined that the aortic valve velocity time integral was 88.1 cm. This correlates well with the sonographer-determined aortic valve velocity time integral of 85.6 cm. Using the velocity time integrals, the calculated aortic valve area from the Continuity Equation was 0.8 cm². My finding of severe aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation

correlates with the findings of Dr. Garg who also found an aortic valve area of about 0.8 square centimeter by the Continuity Equation. Using the peak velocity determinations, the calculated aortic valve area from the Continuity Equation was 0.7 cm². This study was diagnostic of severe aortic stenosis with an aortic valve area of less than 1.0 cm² by the Continuity Equation.

....

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question D.5. That is, the transesophageal echocardiogram of August 17, 2011 conclusively demonstrated an aortic valve area of less than 1.0 square centimeter by the Continuity Equation with comments as above. An echocardiographer could not reasonably conclude that the aortic valve area was not less than 1.0 cm² on this study even taking into account inter-reader variability when appropriate measurements and calculations are performed.

After reviewing the entire Show Cause Record, we find claimant has failed to meet his burden of demonstrating that he is entitled to Matrix A-1 benefits. The Settlement Agreement requires that a claim for benefits based on damage to the aortic valve be reduced to Matrix B-1 if the claimant had aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. See Settlement Agreement § IV.B.2.d. (2) (c)i)e).

Here, the report of claimant's August 17, 2011 echocardiogram notes that Mr. Schaupp had aortic stenosis with "an aortic valve area of ... about 0.8 cm sq by the continuity equation." In audit, Dr. Parmar reviewed this echocardiogram and concluded that it demonstrated aortic stenosis. In addition, the

Technical Advisor reviewed claimant's echocardiogram and determined, "This study was diagnostic of severe aortic stenosis with an aortic valve area of less than 1.0 cm² by the Continuity Equation."⁹

Although claimant takes issue with the auditing cardiologist's failure to state specifically that the presence of aortic stenosis was determined by use of the Continuity Equation, he does not dispute that the report for his August 17, 2011 echocardiogram unequivocally states that his aortic valve area was less than one square centimeter by the Continuity Equation and thus revealed the presence of aortic stenosis as defined by the Settlement Agreement. Equally significant, none of claimant's physicians ever disputes that Mr. Schaupp's echocardiogram reveals the presence of aortic stenosis as defined by the Settlement Agreement. As claimant does not dispute the presence of aortic stenosis as defined by the Settlement Agreement prior to Mr. Schaupp's aortic valve surgery, the Settlement Agreement mandates that claimant's Level III claim be reduced to the B Matrix.¹⁰

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable

9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

10. For this reason, we reject claimant's assertion that the Trust failed to follow the reasonable medical basis standard. We also reject the assertion that deference should be given to the attesting physician because claimant's attesting physician made no finding as to the August 17, 2011 echocardiogram.

medical basis for finding that he did not have aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation. Therefore, we will affirm the Trust's denial of Mr. Schaupp's claim for Matrix A, Level III benefits.